Medical Adult Informed Consent

North Dakota Department of Human Services
Information for People Who Take Part in Research Studies

The following information is being presented to help you decide whether or not you want to be a part of a research study. Please read carefully. Anything you do not understand, ask the doctor.

Title of Study:

Doctor in Charge of Study:

Other Doctors or Staff:

Study Location(s):

Sponsor:

General Information about the Research Study

The purpose of this research study is to…*(explain completely)*

You are being asked to take part in this study because… *(explain why this person)*

You may want a friend or family member to read the form and talk to the study doctor with you. You can also talk to your personal doctor about what you should do. Talking things over can help you make the right choice.

The time you will need to spend in this research study will be about:

The number of people that might take part in this study at this local site is:

Screening Phase *(Please delete if not applicable.)*

If you decide to participate in this study, you will be required to review this informed consent, discuss the study and your possible participation with the study doctor and study nurse. If you are interested in participating, this informed consent must be signed before any study-related test or procedure can be done. After signing this informed consent, medical tests will be completed to help determine if you meet the requirements to be in the study. These tests which are called "screening tests" are described below.

(Please list any screening tests that will be done.)

Plan of Treatment

Your **regular medical treatment** will not actually be part of the research study but will prepare you for the study. Your regular medical treatment will include:

(Describe pre-treatment procedures if applicable; such as drug-washout period, discontinuation of certain medications, changes in certain day to day functions, etc. Also describe treatment, drug, dosage form, route of administration, radiation type and dose; special diets; biopsies, operations; frequency, how often/day, absolute duration of treatment).

The **experimental treatment** that you will receive by taking part in this research study is:

(Describe drugs, devices, procedures that are not part of standard treatment, e.g., experimental drugs, dosage forms, radiation types and doses; special diets; biopsies/operations, extended hospitalization; how often/day, absolute duration of treatment).

Use of Placebo Drug *(Delete this section if you are not using a placebo.)*

Some research studies compare a placebo's effects with effects of *(experimental drug)*. A placebo is an inactive compound that looks exactly like the *(experimental drug),* but will probably have no effect on your body. This research study has a placebo group.

Your chance of receiving the placebo instead of *(experimental drug)* is: *(Explain the odds.)*

The placebo might cause you harm if there is a regular treatment for your disease that you do not receive because you are taking the placebo. This possibility *(applies/does not apply)* to you because regular treatment (*is/is not)* available for your disease.

Storage of Blood and/or Tissue Samples *(Delete this section if it does not pertain to you.)*

Some of your blood and/or tissues that are collected during this research study may be used by the study doctor and/or the drug company to increase their knowledge of your disease and the effects of *(experimental drug)* upon it.

By participating in this research, blood and/or other body tissues will be removed from you, with the tissue and cells analyzed and used by the Investigators and/or sponsors. Your cells or tissue may be used for the commercial development of new therapies or treatment for disease. By signing this consent form, you agree to allow the Investigators to analyze and use your tissue(s) as described for the purpose stated.

Genetic Testing of Blood and/or Tissue Samples *(Delete this section if it does not pertain to you.)*

Genetic research is an important way to try to understand the role of genes in human disease. There are several things you should know before allowing your tissues, cells or blood to be studied or to be stored for future study.

Genetic research serves a number of purposes. These include medical knowledge, public health tracking and the development of new drugs, tests and treatments. Any drugs, tests or treatments that are developed might make money for the department, but you will not share in any profits the department might receive from such commercial products. Information gained from tests of your genetic material (or DNA) will be used for research.

(If the samples will be unlinked to the patient's identity, use the following paragraphs. ***Please Note****: An initial line is provided at the end of the section so that the subject can indicate that he/she chooses to have genetic testing done and that the genetic testing has been adequately explained to him/her.)*

1. Once the sample is taken, it will forever be separated or "unlinked" from your name. This will protect your confidentiality and anonymity; it will also have other consequences:

2. Suppose the scientists discover that your blood sample carries a gene for a disease. Because the sample is anonymous—it is not labeled with your name or any code—the North Dakota Department of Human Services will not be able to provide you with this information. In other words, because the blood sample has been made anonymous, information about it cannot be communicated to you. If you are concerned about a potential genetic disease or problem, you and your doctor might choose to test specifically for it; this would require additional blood or tissue samples. You should discuss this option with your doctor or genetic counselor.

3. Neither can such information be communicated to your family members. Genetic information about you will often apply (in one degree or another) to family members.

4. Even though your name will not be connected to the tissue or blood sample, other information about you might still be connected. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to scientists studying your tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your racial or ethnic group.

5. You can refuse to allow your tissue or blood to be studied or saved for future study. Once you agree to let scientists use your tissues, however, it will be impossible for you to withdraw from any research project using your tissue or blood. This is because the samples will have been made anonymous; it will not

be possible to find your sample to withdraw it.

Participant's Initials

(If the samples will be linked to the patient's identity but the patient will not be recontacted, use the following paragraphs. ***Please Note****: An initial line is provided at the end of the section so that the subject can indicate that he/she chooses to have genetic testing done and that the genetic testing has been adequately explained to him/her.)*

1. Your tissue, cell or blood sample will be stored under your name or a number linked to your name. Your confidentiality will be protected at least to the extent required by law. Your records might be reviewed by government officials or by corporate research sponsors. The North Dakota Department of Human Services collaborates with many other organizations, and information is sometimes shared among them. No information shared with other investigators will include your name or other public identifier, however.

2. Genetic research may affect your ability to get or keep health insurance. For instance, information about your DNA might result in discrimination that would make it difficult for you to obtain health insurance in the future. You will still be responsible for paying for health care. However, the North Dakota Department of Human Services will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

3. You have the right to refuse to allow your tissue or blood to be studied or saved for future study. You may withdraw from a study at any time, and remove from research use any samples that contain identifiers. This means that while the Department of Human Services might retain the identified samples, they would not be used for research. Samples without identifiers might still be retained for research; a different process or consent form is usually used in such cases.

4. Genetic information about you will often apply (in one degree or another) to family members. It is not generally the Department's policy to provide genetic information about you to your family members. However, certain studies, called "pedigree studies", share such information among family members. For this and related research you will be asked if you are willing to share your genetic information with your family members.

5. In addition to your name, other information about you might be connected to your blood or tissue sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your racial or ethnic group.

6. It is possible that more tissue or blood samples will be obtained than are necessary for your treatment. That is, investigators might take samples purely for study purposes.

7. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress, and the possibility of insurance discrimination. The risks of not knowing what is found include not being aware of the need for treatment. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. A process called "genetic counseling" is often useful and appropriate when people are learning about their genes. You should ask your doctor or nurse if you would like to learn more about this.

8. In this study, investigators will ***not*** tell you what they find out about you, nor will they contact you if a test becomes available to diagnose a condition you might have or later develop. For instance, suppose the investigators discover that your tissue sample carries a gene for a disease. Neither the Department nor your doctor will try to contact you or find you to tell you about this gene. While we might not know how to test for a particular disease gene today, we might be able to test for it in the future. The number of genes for which this will be possible in the future is quite large.

9. There are alternatives to notification by investigators. If you are concerned about a potential genetic problem or disease, you and your doctor might choose to test specifically for it; this would require additional blood or tissue samples. You should discuss this option with your doctor or genetic counselor.

10. The presence of a genetic marker does not necessarily mean that a patient will develop a disease. Informing people of all such markers without a medical need can cause unnecessary anxiety. On the other hand, the absence of a marker does not mean that someone will not get the disease. "Genetic diseases" appear as a result of a complex mixture of genes, the environment, behavior and other factors.

_____

Participant's Initials

(If the samples will be linked to the patient's identity but the patient may be recontacted, use the following paragraphs. ***Please Note****: An initial line is provided at the end of the section so that the subject can indicate that he/she chooses to have genetic testing done and that the genetic testing has been adequately explained to him/her.)*

1. Your tissue, cell or blood sample will be stored under your name or a number linked to your name. Your confidentiality will be protected at least to the extent

required by law. Your records might be reviewed by government officials or by corporate research sponsors. The Department of Human Services collaborates with many other organizations, and information is sometimes shared among them. No information shared with other investigators will include your name or other public identifier, however.

2. Genetic research may affect your ability to get or keep health insurance. For instance, information about your DNA might result in discrimination that would make it difficult for you to obtain health insurance in the future. You will still be responsible for paying for health care, however; the Department of Human Services will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

3. You have the right to refuse to allow your tissue or blood to be studied or saved for future study. You may withdraw from a study at any time, and remove from research use any samples that contain identifiers. This means that while the university might retain the identified samples, they would not be used for research. Samples without identifiers might still be retained for research; a different process or consent form is usually used in such cases.

4. Genetic information about you will often apply (in one degree or another) to family members. It is not generally the Department's policy to provide genetic information about you to your family members. However, certain studies, called "pedigree studies", share such information among family members. For this and related research you will be asked if you are willing to share your genetic information with your family members.

5. In addition to your name, other information about you might be connected to your blood or tissue sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your racial or ethnic group.

6. It is possible that more tissue or blood samples will be obtained than are necessary for any treatment. That is, investigators might take samples purely for study purposes.

7. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress, and the possibility of insurance discrimination. The risks of not knowing what is found include not being aware of the need for treatment. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. A process called "genetic counseling" is often useful and appropriate when people are learning about their genes. You should ask your doctor or nurse if you would like to learn more about this.

8. Investigators in this study may try to get in touch with you later to find out about your health in the future, but this is not certain. If you are contacted and want to know what the investigators have learned about your tissue samples, you should understand that the following are the kinds of things the investigators or your health team might tell you:

    a) Information is too sketchy to give you particular details, but you will receive a newsletter informing you about the results of the project.

    b) You carry a gene for a particular disease that can be treated.

    c) You carry a gene for a particular disease for which there is no current treatment. This news might cause severe anxiety or other psychological distress, depending on the severity of the disease.

    d) You carry a gene for a disease and might consider informing relatives that they too, might carry the gene. It can be very difficult to decide whether to share such information with relatives. Genetic counselors can help sort out the various options in such a case.

Also, for any additional, future research, scientists may contact you with a new consent form giving you more information.

9. There are alternatives to notification by investigators. If you are concerned about a potential genetic problem or disease, you and your doctor might choose to test specifically for it; this would require additional blood or tissue samples. You should discuss this option with your doctor or genetic counselor.

10. The presence of a genetic marker does not necessarily mean that a patient will develop a disease. Informing people of all such markers independently of medical need can cause unnecessary anxiety. On the other hand, the absence of a marker does not mean that someone will not get the disease. “Genetic diseases” appear as a result of a complex mixture of genes, the environment, behavior and other factors.

Participant's Initials

(The following paragraph should be included in all genetic research studies whether data will be unlinked or linked.)

These are some of the risks and other facts you need to know about genetic research. There might be other risks we do not know about yet. No direct benefits can be promised from your participation, though some people find satisfaction in contributing to scientific knowledge about human genetics.

Benefits of Being a Part of this Research Study

We cannot tell whether you will benefit from taking *(experimental drug)* because its effects on your disease are not totally understood. On the other hand, by taking part in this research study, you may increase our overall knowledge of your disease and how to treat future patients. *(Explain any further benefits the sponsor details.)*

Risks of Being a Part of this Research Study

You may have unpleasant or harmful side effects from taking *(experimental drug).* The possible side effects of *(experimental drug)* are listed below:

(For each foreseeable research procedure/intervention, describe the immediate and long-term physical, psychological, and social risks/discomforts in order from most likely to occur – least likely to occur.)

You may also have side effects from regular treatment of your disease. This treatment would be *(describe standard treatment*). The possible side effects of this regular treatment are listed below along with your chances of having them and their seriousness compared to your disease.

(For each foreseeable research procedure/intervention, describe the immediate and long-term physical, psychological, and social risks/discomforts in order from most likely to occur --least likely to occur.)

The study doctors will immediately tell you if during the study they discover that *(experimental drug*) causes other new and unknown side effects. If the new findings make it unwise for you to continue, the doctors will stop your treatment. You will then be offered other suitable treatment for your disease if such a treatment is available.

Alternatives of Being Part of this Research Study

Alternatives of being part of this research study is/are: *(list)*

Another alternative is to not participate in this study.

Risk to Unborn Children (*Delete this section if you are not recruiting women of child bearing age.)*

Female Subjects

It is possible that *(experimental drug*) may cause unknown side effects on unborn children now or in the future due to exposure in the womb or there may be a risk to your child if breast feeding. If you are pregnant, become pregnant, or breast feeding while taking part in this research study, tell one of the study doctors immediately.

Male Subjects

The effect of *(experimental drug*) on sperm has not been determined. Male patients should take the same precautions described above to avoid getting your partner pregnant.

All Subjects

In order to participate in this study, you must use reliable birth control methods, such as: *(Please list those methods that are medically reliable.)*

Payment for Being a Part of this Research Study (*Choose the statement that fits*.)

By taking part in this research study, you will be paid (*list the amount of money, other compensation, payment schedule, contingencies for payment, etc.)*

You will not receive cash or other gifts for taking part in this research study.

Costs of Being a Part of this Research Study

You *(will/will not)* be responsible for paying *(hospital/outpatient/other*) costs of participation in this research project. Hospital costs include *(describe)*. Outpatient costs include *(describe*). Other costs include *(describe).*

You *(will/will not*) have to pay certain fees for tests in the research study that are not a part of regular medical care for your condition. These extra tests and procedures add approximately ($ Added Cost) to you.

In Case of Illness or Injury

Call one of the doctors listed on the first page at *[Please fill in telephone number(s).]* in the event you get sick or injured while on this study. If you have an

emergency, go to the closest emergency room or clinic for treatment.

North Dakota Department of Human Services' Injury Statement

In the event that you sustain an injury or illness as a result of participating in this research, please be aware that medical treatment for the injuries or illness may not be available from the North Dakota Department of Human Services (DHS). DHS does not maintain an emergency department nor does it provide medical treatment in all disciplines of medicine. If you become ill or sustain an injury which you believe is related to participation in this research, **immediately** contact one of the persons listed on page 1 of this form, and if emergency care is needed seek emergency attention from your nearest local hospital.

If you believe you are injured as a result of participation in this research and the negligent conduct of a Department employee, you may notify the North Dakota Department of Human Services' Risk Manager at 701-328-2311, who will investigate the matter.

Sponsor Statement

If applicable, insert Sponsor Statement here.

Confidentiality of Your Records

Your research records will be kept *(Describe how)* to protect you privacy to the full extent of the law. However, authorized research investigators, agents of the United States Food and Drug Administration, the Department of Health & Human Services, the North Dakota Department of Human Services' Institutional Review Board, and other entities/individuals as required or authorized by law, may inspect your records from this research project. Doctors, nurses and others involved with your care will also be able to see the research information in your medical record.

Employees of *(sponsor's name)* who supply *(experimental drug)* will also have the right to look at your hospital record.

The results of this research study may be published, but they will not include your name or any other information that may identify you.

Volunteering to Be Part of this Research Study

You should only take part in this research study if you want to take part. If you choose not to participate there will not be any penalty or loss of benefits to which you are otherwise entitled. If you decide you want to stop taking part in the study tell a study monitor as soon as possible. They will want to tell you if there are any dangers in stopping treatment. If you decide to stop, any other suitable treatment for your disease that may exist will be recommended to you.

You may be removed from the study without your consent if: *(describe; new information presented from the sponsor, noncompliance, etc.).*

Questions and Contacts

If you have any questions about this research study, contact *(identify person(s) and their telephone numbers.)*

If you have questions about your rights as a person who is taking part in a research study, you may contact the Chair of the North Dakota Department of Human Services' Institutional Review Board, Dr. Christine Kuchler, at 1-888-328-2662.

Your Consent—By signing this form I agree that:

I have fully read or have had read and had explained to me in language that I understand this informed consent form describing a research project.

I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.

I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.

I will be given a signed copy of this informed consent form, which is mine to keep.

Signature of Participant	Printed Name of Participant	Date
Signature of Witness	Printed Name of Witness	Date

Investigator Statement

I have carefully explained to the subject the nature of the above protocol. I, hereby, certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study and that a medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in this study.

_____	_____	_____
Signature of Investigator	Printed Name of Investigator	Date

Institutional Approval of Study and Informed Consent

This research project/study and informed consent form were reviewed and approved by the North Dakota Department of Human Services' Institutional Review Board for the protection of human subjects. This approval is valid until the date provided below. The board may be contacted at 1-888-328-2662.

Consent Form Approval Date:

Approval Consent Form Expiration Date: (*Your proposed expiration date is subject to IRB review.)*

- If this informed consent form has an "approval expiration date" that expires before the completion of this research study, the Principal Investigator may contact you for your re-consent at the time of expiration.

Consent of Proxy to Participation in Clinical Research Study

Patient/Study: _____("Patient")

Title of Clinical Research Study: _____("Study")

I. DETERMINATION OF INCAPACITY

A. I am the patient's attending physician. I have examined the Patient and have determined that the Patient does not have the capacity to consent to participation in the Study.

_____	_____
Signature of Attending	Printed Name of Attending*

***The PI can be the attending**

B. I am a physician licensed in the State of North Dakota. I do__/do not__concur with the attending physician's determination of incapacity.

_____	_____
Signature of Physician	Printed Name of Physician

II. IDENTIFICATION OF PROXY

A. Informed consent to participate in the Study may be given for the Patient by a Proxy", or substitute decision-maker. A Proxy may be any of the following individuals listed in paragraph B, in the order of priority listed, if no individual in a prior class is reasonably available, willing, or competent to act.

B. Review the following list and write "Proxy" in the space provided to indicate the relationship of the individual who will provide informed consent for the Patient. If an individual with a higher priority exists but is not reasonably available, willing, or competent to act, indicate in the spaces provided the reason that the person is not available and make a note of any contact attempts by staff.

(1) **Health Care Surrogate** designated by Patient: _____

(2) The judicially appointed **guardian** of the Patient, who has been authorized to consent to medical treatment:_____

(3) The Patient's **spouse**: _____

(4) An **adult child** of the Patient, or if the Patient has more than one adult child, a majority of the adult children who are reasonably available for consultation: _____.

(5) A **parent** of the Patient: _____

(6) The **adult sibling** of the Patient or, if the Patient has more than one sibling, a majority of the adult siblings who are reasonably available for consultation:_____

(7) An **adult relative of the Patient who has exhibited special care and concern** for the
Patient and who has maintained regular contact with the Patient and who

is familiar with the Patient's activities, health, and religious or moral beliefs: _____

(8) A **close friend** of the Patient: _____.

C. Informed Consent must be based on the Proxy's informed consent and on the decision the Proxy reasonably believes the Patient would have made under the circumstances.

III. PROXY CONSENT

I am over the age of 18 and willing and competent to make health care decisions for the Patient, including the decision to enroll the Patient in the Study. I have reviewed the attached Informed Consent to Participate in the Study and have had the opportunity to ask any questions regarding the Patient's participation. I certify that signing this informed consent to enroll the Patient in the Study described is not contrary to any written or oral instructions received from the Patient. I believe that this is the decision that the Patient would have made under the circumstances.

_____

Signature of Proxy Date Printed Name of Proxy

_____

Address of Proxy Telephone Number(s)

_____

Signature of Witness Date Printed Name of Witness